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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LOGIE, MICHAEL J	

ART UNIT	PAPER NUMBER
2881	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,974	AMELIA ET AL.	
	Examiner	Art Unit	
	MICHAEL LOGIE	2881	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1,3-5,7-14,17 and 20-41* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,3-5,7-14,17 and 20-41* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 July 2011 has been entered.

Response to Amendment

An “Amendment” was received on 18 July 2011, in response to Office Action of 18 January 2011. Claims 1, 21, 31 and 41 have been amended. Claims 1, 3-5, 7-14, 17 and 20-41 are now pending.

Response to Arguments

Applicant's arguments filed 18 July 2011 have been fully considered but they are not persuasive.

Arguments regarding the rejection of ‘263 in view of Erdman are persuasive and are therefore withdrawn.

Arguments in regarding '263 in view of Zeisler are not persuasive. The general theme of the arguments is that the one-piece insert of '263 does not have two separate parts. The examiner disagrees. First the broadest independent claim 1 merely recites

that the two parts are made of two different metallic materials. Therefore, claim 1 does not require that one piece be niobium or tantalum. Regardless of this point, '263 does teach an insert comprising two separate parts. The first part being the target cavity 1 and the second part of the insert 8 forms a channel in which cooling fluid may circulate (see figure 1 below).

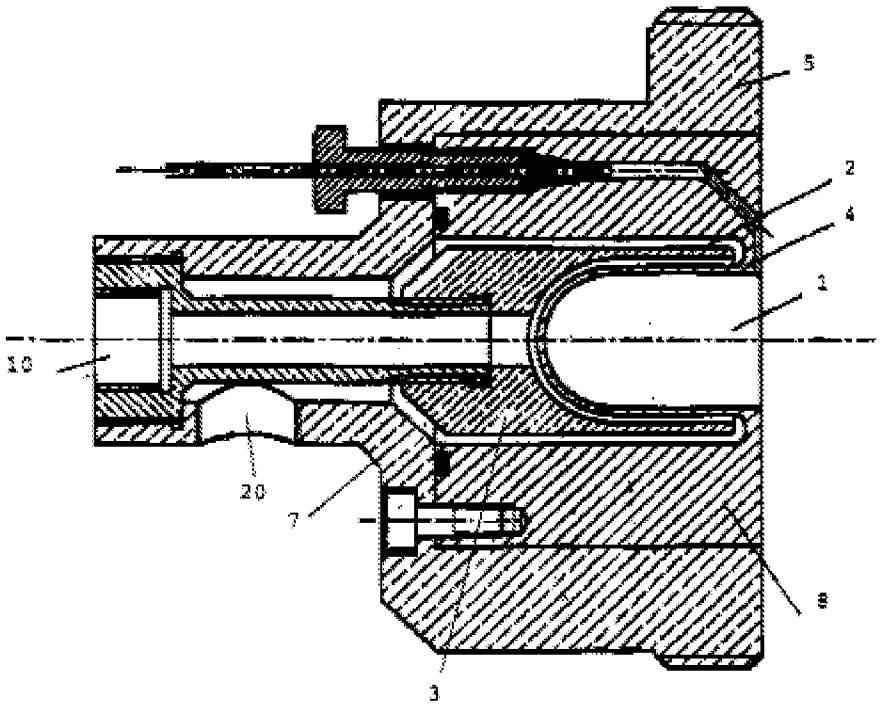

FIG. 1

Therefore because the insert comprises two parts, each having its respective function, one for retaining and another for circulating, the insert of '263 does comprise two separate parts having different functions therein. As pointed out on page 13 of the remarks, “it would be beneficial to use niobium or tantalum for a target chamber insert,

niobium is difficult to machine and therefore a difficult material to use for making an insert of complex design, such as the insert described in BE '263. (Application ¶23). A built up edge may occur on the tools used to machine the niobium, leading to high tool wear and/or breakage, and the use of electrical discharge machining is not effective. (Id.). Therefore, one of ordinary skill in the art at the time of the filing of this application would not have believed that the complex insert of BE '263 could be made of niobium or tantalum" and then on pages 14-15 the remarks recite: "At most, one of ordinary skill reading Zeisler would have believed that niobium has beneficial material properties, and would have attempted to manufacture the insert of BE '263 from niobium. However, as discussed above, niobium, tantalum, and other similar materials are difficult to machine, and one of ordinary skill would not have believed that niobium or tantalum was an appropriate material for manufacturing the complex target chamber insert of BE '263".

As made clear by the remarks niobium or tantalum, although a beneficial material is difficult to manufacture and would therefore be impractical to make a one-piece system (comprising two parts as discussed above). The examiner agrees. However, given that '263 recognizes an integral insert having two separate parts, one would have been motivated to find a way to implement a more beneficial material such as niobium or tantalum into the two part insert of '263. Zeisler solves this problem by providing an insert having the target chamber made of niobium and a holder ring made of copper. As pointed out in the remarks, one would have appreciated the beneficial properties of using niobium as the target chamber (niobium is more ductile and has a higher tensile strength and better conductivity than titanium (see page 450, top of the first column of

Zeisler)), while using a copper support ring allowing for the manufacture of a target chamber and cooling structure where it would be very difficult to do using niobium in the one piece insert of ‘263. That is, ‘263 already teaches a separate two part (channel and cavity), however it fails to teach the two part system made of different metallic materials. Zeisler makes a cavity out of niobium and a support ring from copper which as seen from figure 2 provides a cooling path for the cavity. Since '263 teaches the elongated cavity having a second part surrounding the cavity (cooling channel around elongated cavity formed by insert 8), one would not be motivated to change this structure as it has the advantageous quality of increasing the power transmitted to the target while keeping the cavity cool. However, acknowledging that Zeisler uses different metallic materials for the cavity and the channel, one would have been motivated to modify the insert of ‘263 such that the cavity could be made of niobium and the channel (holder ring) be made of copper as in Zeisler and it would yield predictable results (i.e. a modified version of ‘263 having a niobium cavity and a copper channel forming means allowing for a cavity with "more ductile and has a higher tensile strength and better conductivity than titanium”).

Therefore the remarks are unpersuasive and the prior rejection holds as will be discussed in further detail considering the amendments below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 9-11, 13, 14, 17, 20-22, 27-32 and 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over BE 1011263 A6 (translation submitted by applicant on 12/16/2009)(herein '263) and further in view of Zeisler et al. (Zeisler et al., "A water-cooled spherical niobium target for the production of [18F]fluoride", Applied Radiation and Isotopes 53 (2000) 449-453)(copy of publication submitted with the office action of 10/01/2010) or in alternate Erdman USPN 6,586,747).

In regards to claim 1, '263 teaches an irradiation cell (fig. 1) for producing a radioisotope of interest through the irradiation of a target material by a particle beam (page 2, lines 8-12), the irradiation cell comprising a target body (page 5, line 14), a diffuser configured to provide a path for a cooling medium (page 4, lines 25-27), and a removable metallic insert (fig. 1,8, figure 2 shows an exploded view thus removable, further an insert is removable by definition) comprising a cavity designed to house the target material (page 4, lines 10-11 and page 4, lines 28-30 teach the cavity holds the target and the cavity is made with an insert) and the cavity closed by an irradiation window (page 4, lines 10-11 teach a charged particle beam sent to a target within a cavity, thus the cavity must inherently be closed by an irradiation window to allow the charged particle beam access to the cavity), the metallic insert configured to be inserted in and removed from the target body (where an insert can be inserted, it can be removed from the body, thus the limitation is interpreted to be met), wherein the

removable metallic insert comprises of at least a first part (the insert part forming the target cavity is the first part) and a second part (portion of the insert forming the cooling channel see page 5, lines 7-14), the first part having an elongated cavity that is longer in a direction parallel to the particle beam that irradiates the target than in a direction perpendicular to the particle beam (as seen in figure 1) and the second part partially surrounding the first part and forming a channel configured to guide a cooling medium (page 5, lines 7-14, see figure 1. second part does not surround the back of the cavity or the window portion).

'263 differs from the claimed invention by not disclosing the metallic insert having at least two separate metallic parts of different materials.

However, Zeisler teaches the metallic insert having at least two separate metallic parts of different materials (fig. 2, page 451, wherein the first part is the target chamber 5 and the second part is the holder ring 3).

Zeisler modify '263 by providing a two part insert of different materials.

Since both '263 and Zeisler teach target chambers, it would have been obvious to one of ordinary skill in the art to have the two part arrangement of Zeisler in '263 at the time the invention was made because it would modify the insert of ‘263 such that the cavity could be made of niobium and the channel (holder ring) be made of copper and it would yield predictable results (i.e. a modified version of ‘263 having a niobium cavity and a copper channel forming means allowing for a cavity with "more ductile and has a higher tensile strength and better conductivity than titanium”).

In regards to claims 3, 22 and 32, '263 teaches wherein said cell further comprises a coolant supply configured to supply the cooling medium (fig. 1, 10) and the coolant supply in connection with the channel the diffuser device surrounding the first part and being configured to guide the cooling medium around the first part (page 5, lines 1-6), and wherein the second part surrounds both the first part and the diffuser device in a manner to form a return path for the cooling medium between the diffuser device and the second part (page 5, lines 7-14).

In regards to claims 9, 27 and 37, '263 teaches wherein the first part comprises a flat, circular and ring-shaped portion having an inner circular edge and an outer circular edge, a cylindrical portion rising perpendicularly from the inner circular edge of the flat portion, and a hemispherical portion being on top of the cylindrical portion, the cavity being formed inside the cylindrical and hemispherical portions (as seen in figure 1).

In regards to claims 10 and 28, '263 differs from the claimed invention by not disclosing wherein the cylindrical portion has a wall thickness comprised between .3 and .7 mm.

However, Zeisler et al. teach wherein the cylindrical portion has a wall thickness comprised between .3 and .7 mm (page 450, section 4 shows an equation wherein the wall thickness is a variable, as such .3 to .7 mm is a possible range of wall thicknesses).

Zeisler modify '263 by providing a two part insert of different materials.

Since both '263 and Zeisler teach target chambers, it would have been obvious to one of ordinary skill in the art to have the two part arrangement of Zeisler in '263 at the time the invention was made because it would modify the insert of ‘263 such that the

cavity could be made of niobium and the channel (holder ring) be made of copper and it would yield predictable results (i.e. a modified version of '263 having a niobium cavity and a copper channel forming means allowing for a cavity with "more ductile and has a higher tensile strength and better conductivity than titanium").

In regards to claims 11 and 29, '263 teaches wherein the second part has the form of a hollow cylinder having two flat sides essentially perpendicular to a cylindrical side, the cylinder being connected by one flat side against the flat portion of the first part (as seen in figure 1 and discussed in citations herein above).

Claims 13 and 38 is taught as in the citations above.

In regards to claim 14, the device differs from the claimed invention by not showing the element comprises a material selected from the group consisting of stainless steel. It would have been obvious for the element to be composed of a material selected from the group consisting of stainless steel, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use. In re Leshin, 125 USPQ 416.

In regards to claim 17, '263 teaches filling the cavity volume of the irradiation cell with about 50% of target material before starting irradiation (because the cavity container can be filled, it is capable of being filled to 50% of its volume).

In regards to claims 20 and 40, '263 teaches wherein the cell further comprises a supply tube for a cooling medium and, in connection with the supply tube, a diffuser device mounted on one end of the supply tube (fig. 1, supply tube 10 and diffuser 3), the diffuser device surrounding the first part, the diffuser element being configured to guide

the cooling medium around the first part (page 4, lines 23-27), and wherein the second part surrounds both the first part and the diffuser element in a manner to form a return path for the cooling medium between the diffuser element and the second part (see figure 1).

In regards to claim 21, '263 teaches an irradiation cell (fig. 1) for producing a radioisotope of interest through the irradiation of a target material by a particle beam (page 2, lines 8-12), the irradiation cell comprising a target body (page 5, line 14), a diffuser for providing a path for a cooling medium (page 4, lines 25-27), and a removable metallic insert (fig. 1,8, figure 2 shows an exploded view thus removable, further an insert is removable by definition) comprising a cavity designed to house the target material (page 4, lines 10-11 and page 4, lines 28-30 teach the cavity holds the target and the cavity is made with an insert), the cavity closed by an irradiation window (page 4, lines 10-11 teach a charged particle beam sent to a target within a cavity, thus the cavity must inherently be closed by an irradiation window to allow the charged particle beam access to the cavity), the metallic insert configured to be inserted in and removed from the target body where an insert can be inserted, it can be removed from the body, thus the limitation is interpreted to be met), the metallic insert comprising being composed of at least a first part (the insert part forming the target cavity is the first part) and a second part (portion of the insert forming the cooling channel see page 5, lines 7-14), the first part having a cylindrical portion and a hemispherical portion forms a cavity that is elongate in a direction parallel to the particle beam that irradiated the target (fig. 1, 1 also see page 4, lines 10-11) and the second part being a generally

cylindrical hollow member disposed concentrically about the first part (second part surrounding diffuser, as seen in figure 1, also see page 5, lines 7-14) a material selected from the group consisting of titanium (page 4, lines 28-29), with the second part disposed around at least a portion of the elongate cavity of the first part and the first and second parts forming a channel configured to guide a cooling medium (page 5, lines 7- 14 and as seen in figure 1).

'263 differs from the claimed invention by not disclosing wherein the removable metallic insert comprises at least two separate metallic parts of different materials, the first part comprising a material selected from the group consisting of niobium and tantalum.

However, Zeisler teaches wherein the removable metallic insert comprises at least two separate metallic parts of different materials, the first part comprising a material selected from the group consisting of niobium and tantalum (fig. 2, page 451, wherein the first part is the niobium target chamber 5 and the second part is the holder ring 3).

Zeisler modify '263 by providing a two part insert of different materials.

Since both '263 and Zeisler teach target chambers, it would have been obvious to one of ordinary skill in the art to have the two part arrangement of Zeisler in '263 at the time the invention was made because it would modify the insert of ‘263 such that the cavity could be made of niobium and the channel (holder ring) be made of copper and it would yield predictable results (i.e. a modified version of ‘263 having a niobium cavity

and a copper channel forming means allowing for a cavity with "more ductile and has a higher tensile strength and better conductivity than titanium").

Claim 31 is broader in scope than independent claim 1 and is therefore rejected for the same reasons above.

Claim 41 is rejected for the same reasons cited above in claim 21. Further .263 teaches wherein the cell further comprise a supply tube configured to supply a cooling medium and, in connection with the supply tube, a diffuser device mounted on one end of the supply tube, the diffuser device surrounding the first part, the diffuser element being configured to guide the cooling medium around the first part, and wherein the second part surround both the first part and the diffuser element in a manner to forma return path for the cooling medium between the diffuser element and the second part (page 4, lines 23-27, page 5, lines 7-14 and figure 1, wherein the first part of insert forms the cavity and the second part of insert 8 forms the cooling channel and surround the cavity 1 and the diffuser 3).

Claims 4, 5, 7, 8, 12, 23-26, 30 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over BE 1011263 A6 (translation submitted by applicant on 12/16/2009)(herein '263) and Zeisler et al. (Zeisler et al., "A water-cooled spherical niobium target for the production of [18F]fluoride", Applied Radiation and Isotopes 53 (2000) 449-453)(copy of publication submitted herewith) and further in view of Schlyer et al. (USPN 5,917,874).

In regards to claims 4, 5, 7, 8, 12, 23-26, 30 and 33-36 the combined invention fails to teach coupling of the two parts by o-rings gold foil, bolts, and welding.

Schyler et al. teaches coupling by bolts (col. 4, lines 18-22).

Although Schlyer et al. only describes coupling by bolts, fixing means such as gold foil, bolts and welding are commonly used in assembling devices and integration is part of the common knowledge of a skilled person. Thus having such fixing means would have been obvious to one of ordinary skill in the art because the substitution of one known element for another would have yielded predictable results.

Schyler modifies the combined invention by providing fixing means between two parts.

Since both the combined invention and Schyler teach irradiating target chambers, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the fixing means of Schyler in the combined device because the simple substitution of one known element for another (i.e. integral parts for two separate parts and joining them therein) would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL J. LOGIE whose telephone number is (571)270-1616. The examiner can normally be reached on 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Kim can be reached on 571-272-2293. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. L./
Examiner, Art Unit 2881